Management of ear keloids using custom-molded pressure clips: a preliminary study

Volkan Tanaydin, Carlo Colla, Andrzej Piatkowski, Jop Beugels, Nicole Hendrix, Eric van den Kerckhove, Greg C. G. Hugenholtz, et al.

European Journal of Plastic Surgery

ISSN 0930-343X

Eur J Plast Surg
DOI 10.1007/s00238-014-0943-7

Springer

Eur J Plast Surg
DOI 10.1007/s00238-014-0943-7

ORIGINAL PAPER

Management of ear keloids using custom-molded pressure clips: a preliminary study

Volkan Tanaydin · Carlo Colla · Andrzej Piatkowski · Jop Beugels · Nicole Hendrix · Eric van den Kerckhove · Greg C. G. Hugenholtz · René D. W. J. van der Hulst

Received: 9 December 2013 / Accepted: 21 February 2014

Abstract
Background The application of mechanical pressure by compression devices has gained popularity in the treatment of keloid scars. In this present study, we analyze the long-term efficacy of our custom-molded pressure clip for ear keloids. Our secondary objective is to identify risk factors for the failure of the treatment in the group of the recurrence.
Methods The patient group consisted of 9 men and 19 women with a mean age of 27 years and a mean follow-up of 8.5 years. For evaluation of the scars, scoring ratings, Patient and Observer Scar Assessment Scale (POSAS), and SF8-questionnaire have been used.
Results Follow-up observations showed that 71 % were treated successfully. There were significant differences in the Fitzpatrick scale, cause of the ear keloids, overall opinion, and openness for re-treatment between the recurrence and nonrecurrence group. Furthermore, treatment with our custom-molded pressure ear clip resulted in a statistically significant improvement of all the item scores of the POSAS in both the patient and observer scales. Severe complications such as infections or necrosis were not noted.
Conclusions In this study, we show that the results of adjuvant pressure therapy with our custom-molded ear clips are comparable with the recurrence rates of other studies recently published. The strength of this study is the long follow-up.
Level of Evidence: Level III, therapeutic study

Keywords Ear keloids · Pressure therapy · Pressure clips · POSAS · Preliminary study · Keloid · Therapy

Introduction

Keloids are a disease well known to mankind for a long time. The first description of abnormal scar formation in the form of keloids was recorded in the Smith papyrus regarding surgical techniques in Egypt around 1,700 B.C. Even almost 4,000 years later, management of keloids remains a challenge for both the clinician and the patient. Keloids are defined as benign fibrous skin tumors which grow at the site of a skin wound but beyond the margins of the wound. The aspect is mostly darker in color in comparison to normal skin. It is known that keloids are the result of a dysfunctional scarring process that leads to an overabundance of collagen deposits [1], which results in growing of this scar causing discomfort and disfigurement.

V. Tanaydin and C. Colla contributed equally to this work.

V. Tanaydin (✉) · C. Colla · A. Piatkowski · J. Beugels · N. Hendrix · G. C. G. Hugenholtz · R. D. W. J. van der Hulst
Department of Plastic, Reconstructive and Hand Surgery, Maastricht University Medical Centre, P.O. Box 5800, 6202, AZ Maastricht, The Netherlands
e-mail: V.Tanaydin@gmail.com

E. van den Kerckhove
Department of Rehabilitation Sciences, KU Leuven, FABER Tervuursevest 101, Heverlee, 3001, UZ Leuven, Belgium

E. van den Kerckhove
Department of Burns and Rehabilitation, Campus Gasthuisberg, Herestraat 49, 3000 Leuven, Belgium

Published online: 11 March 2014

The exact incidence of keloids remains to be unknown, but several studies show an incidence of approximately 2–2.5 % [2, 3] and at 4.5 to 16 % in the black and Hispanic populations in several large series [4]. Different types of injury can be a cause of keloids: e.g., ear piercing, burns, trauma, surgery, tattooing, vaccination, or even insect bites. Since skin and wound tension is considered a critical factor in the formation of keloids, the most susceptible sites are the central chest, the back, the shoulders, and, interestingly, also the ear lobes [5].

Numerous therapeutic modalities have been used to treat auricular keloids including intralesional corticosteroid injection [6], pressure therapy [7, 8], cryotherapy [9], radiotherapy [3, 10, 11], laser therapy [12, 13], surgical excision, or a combination [6, 14, 15]. The variety of treatments for keloids suggests that none of these widely used therapies is satisfactory [7, 16–18]. One of the major problems encountered during the therapy of earlobe keloids is the problematic and even sometimes impossible way of applying pressure to the keloid. This is mostly due to the peculiar shape of the ear that makes it difficult to give compression. This results in higher rates of therapy failure and recurrence of keloids. Nowadays, new ear pressure clips have been developed [16–19] with different results in terms of effectiveness, comfort, and cosmetic appearance.

In recent years, there has been the development of adjuvant pressure therapy by using a custom-made methyl methacrylate stent as published by Kadouch et al. [16]. This study uses a different device which shares the same principle as the device published by Kadouch et al. but includes more patients and has a longer follow-up.

Most of the pressure devices lack control of the amount of pressure applied to the keloid; however, our device has been optimized in order to allow the pressure to be adjusted. Furthermore, using our device makes it possible to also treat retro-auricular keloids (Figs. 1 and 2).

In this present study, we analyzed the long-term efficacy of this pressure device for ear keloids. Our secondary objective was to identify risk factors explaining for the failure of the treatment in the recurrence group.

Material and methods

Between 2003 and 2006, we treated 28 consecutive patients using a combination therapy of excision and our custom-molded pressure clip. Two weeks after excision of the keloid, a plaster cast of the ear was made. Then, by using the cast as a mold, a silicon liner was fabricated matching the surface of the ear. When fitted over the ear, the silicon liner was covered on both sides of the ears with two custom-made artificial auricles: one pre- and one retro-auricular. The fitting of which was enabled by the thermoplastic properties of the fabric as well as by a one-way click–and–fit system. In addition, these auricles could be pressure adjusted by a U-shaped screw–and–pin system.

Fig. 1 Our custom-molded pressure clip. Note the different pressure mechanisms

The custom-molded clips ensure a hydrated environment due to the choice of a silicon fabric. In addition, their effectiveness relies on the adjustability of the pressure on exactly those points where keloid recurrence is anticipated. Hence, the pressure can be variably adjusted during daytime ensuring a maximum capacity of the device to reduce keloid recurrence. The pressure is adjusted based on the patient's discomfort. However, we anticipated that most of the discomfort is related initially to the patient's awareness of the clip upon wearing. Therefore, we designed a habituation scheme: On the first day, the pressure is maximized to enable a wearing time of 1 h. The next day, it is adjusted so that it can be worn for 2 h, and then for 3 h the following day and so on until it is worn for 12 h consecutive with a minimum amount of discomfort. After 2 weeks, the pressure is augmented again until the pressure area in and around the scar blanches, but without discomfort and pain. This is the onset of therapy. Subsequently, any evidence of keloid recurrence is closely monitored in follow-up. If present (i.e., scar thickness increases),

Fig. 2 *Left side*: keloid in the upper pole/helix of the ear and retro-auricular area. *Right side*: appearance after therapy with our custom-molded pressure ear clip

this means that the scar area may not be targeted properly and pressure adjustments are made accordingly either by relocating the pressure or by increasing it. During therapy, an interdisciplinary team assessed the keloid every 3 months in our outpatient clinic. The therapy is continued for an average of 12–15 months (12–16 h/day). Normally, the scar is then free of edema, colorless, and pliant. Post-therapy follow-up is pursued each year for 3 years. Within therapy, discontinuation standards comprise the following: (1) keloid recurrence in spite of corticoid injections, (2) more than two times therapy-related pressure ulcer occurrence, and (3) no-show of patients in follow-up. Before participation in the present study, informed consent was obtained from all patients and the medical record was retrieved from the archive. Follow-up was performed at the outpatient clinic or by telephone interview.

Statistical analysis

Continuous variables are presented as means with standard deviations or as medians with interquartile ranges. Categorical variables are presented as percentages. Continuous variables

Table 1 Patient characteristics and risk factors between the recurrence and nonrecurrence groups and *P* values. (The figures in brackets mean the standard deviation or the first and third quartile)

	Recurrence, *N*=8 (29 %)	Nonrecurrence, *N*=20 (71 %)	*P*
Gender (male)	50 %	25 %	0.37
Age (years)	25 (8)	27 (11)	0.50
Positive family history (%)	0	15	0.54
BMI (kg/m^2)	22 (5)	24 (4)	0.22
Fitzpatrick scale	III (III–IV)	III (II–III)	0.05*
Anatomical location (%)			0.32
Upper pole	25	20	
Lobule	25	55	
Retro-auricular	50	25	
Cause (%)			0.04*
Ear piercing	25	60	
Otoplasty	75	25	
Trauma	0	15	
Previous treatment (%)			0.76
None	63	65	
Surgical excision	13	10	
Injections	25	15	
Brachytherapy	0	10	
Patient compliance (%)			0.60
<8 h a day	13	15	
8–12 h	50	30	
>12 h	38	55	
Therapy duration (months)	18 (10)	15 (6)	0.44
Comfort	5.00	6.75	0.11
Appearance	4.13	5.25	0.23
Overall opinion	4.63	8.05	0.02*
Open for re-treatment (yes)	37.5 %	100 %	0.01*
Enhanced quality of life (yes)	25 %	60 %	0.21

*$p \leq 0.05$

were compared between groups using unpaired Student's *t* tests or Mann–Whitney *U* tests as appropriate. Categorical variables were compared between groups using chi-square tests or Fisher's exact tests as appropriate. Changes in continuous variables before and after treatment were compared using paired Student's *t* tests. A *P* value of 0.05 was considered statistically significant. Statistical analysis was performed using SPSS version 20.0.

Results

The patient group consisted of 9 men and 19 women with a mean age of 27 years (18–66 years) and a mean follow-up of 8.5 years (6.9–12.3 years). All patients were classified

Table 2 Identifying risk factors between the recurrence and nonrecurrence groups and *P* values

Patient scale	Before therapy	Last follow-up	*P* value
Pain	4.25	1.11	<0.001*
Itching	5.04	2.00	<0.001*
Color	5.79	1.54	<0.001*
Stiffness	8.39	3.25	<0.001*
Thickness	8.54	3.00	<0.001*
Irregularity	8.00	2.54	<0.001*
Overall opinion	9.14	3.07	<0.001*

*$p \leq 0.05$

Table 3 Comparison of the POSAS observer scale before therapy and the last follow up and *P* values

Observer scale	Before therapy	Last follow-up	*P* value
Vascularity	3.82	2.18	<0.001*
Pigmentation	3.04	1.82	0.01*
Thickness	6.89	3.32	<0.001*
Relief	5.75	3.00	<0.001*
Pliability	6.93	3.18	<0.001*
Surface area	7.07	3.25	<0.001*
Overall opinion	7.00	3.29	<0.001*

*$p \leq 0.05$

according to the Fitzpatrick scale (types I–VI). Additional questions in terms of comfort, appearance, and overall opinion of the ear clip have been scored from 1 (worst) to 10 (best) and are documented in Table 1. Furthermore, by using the SF-8 questionnaire, we asked the patients if they would undergo the same treatment again and if the treatment had affected their quality of life [20]. Follow-up observations showed that 20 patients (71 %) were treated successfully and 8 patients (29 %) developed recurrence. For evaluation of possible differences between the recurrent and nonrecurrent group, variables defining the patient population were evaluated and risk factors for failure of treatment were identified. There were significant differences in the Fitzpatrick scale, cause of the ear keloids, overall opinion, and openness for retreatment between the recurrence and nonrecurrence group. No significant differences were found for the further parameters. In the nonrecurrence group, patients are more compliant to therapy than the nonrecurrence group (55 % >12 h of wearing) compared to the recurrence group (38 % >12 h of wearing). In the nonrecurrence group, patients were generally satisfied (8.05; overall opinion), but disliked the appearance of the ear clip (5.25; appearance). The comfort of the ear clip was acceptable, but should be improved (6.75; comfort). In the recurrence group, patients were generally discontent (4.63; overall opinion). However, comfort and appearance were judged similarly as in the nonrecurrence group. Of note, 37.5 % of the patients in the recurrence group repeat the treatment and 25 % of these patients experienced an enhanced quality of life.

Table 4 Total scores of the POSAS before therapy, on last follow-up, and relative reduction in POSAS as well as *P* values

	Recurrence	Nonrecurrence	*P* value
POSAS score before treatment	81.50	92.90	0.08
POSAS score last follow-up	56.13	28.70	0.01*
POSAS score reduction	25.38	64.20	0.01*

*$p \leq 0.05$

Table 5 Side effects from using our custom-molded pressure ear clip

Side effect	Number (%)
None	6 (21 %)
Discomfort	17 (61 %)
Pruritis	4 (14 %)
Skin irritation	7 (25 %)
Transient pressure ulcer	5 (18 %)
Scarring with poor cosmetic results	0 (0 %)
Infection	0 (0 %)

In this study, the Patient and Observer Scar Assessment Scale (POSAS) was used to evaluate the scars (Table 2, 3, and 4). The POSAS is a comprehensive scale designed for the evaluation of all types of scars by professionals as well as patients [21, 22]. Treatment with our custom-molded pressure ear clip resulted in a statistically significant improvement of all

Fig. 3 Pressure ulcer as a complication

the item scores of the POSAS in both the patient and observer scales. The total score of the POSAS before treatment showed no statistically significant differences between the recurrence and nonrecurrence group. Lastly, the complaints or side effects of the ear clips were evaluated and documented in Table 5. Sixty-one percent of the patients were found to have discomfort during the application of the pressure clip. A relatively small number of patients complained about pruritus (14 %), skin irritation (25 %), and transient pressure ulcer with no permanent damage or scarring to the ear (18 %, Fig. 3). Severe complications such as infections or skin necrosis leading to scarring and poor cosmetic results were not noted.

Discussion

Since the use of pressure therapy by Ambroise Paré for the first time in 1678 [23], the application of mechanical pressure by compression devices has gained popularity in the treatment of keloid scars. Surgery alone leads to recurrence rates ranging from 45 to 100 % [24]. Combined with compression devices, recurrence rates drop to 10–20 % [16, 18]. Nowadays, pressure earrings are widely used as an adjunct to surgery in the treatment of auricular keloids. Chalian et al. [7] postulated that the ideal characteristics of pressure earrings should be "*noninflammable, strong enough to resist distortion, light in weight, comfortable to wear, and easy for the patient to apply and remove. It must provide uniform adjustable compression and it must not interfere with normal hearing. It should also be inexpensive, easy to fabricate, esthetically acceptable, and easy to clean for proper hygiene*."

Various compression devices have been described in literature: spring pressure earrings [8], silicone-sheeted earrings [6], custom-made silicone ear mold [19], magnetic disks [18, 25], acrylic resin devices [15, 26], U loop devices [17], Zimmer splintage [27], aluminum finger splints [28], and methyl methacrylate stents [16, 29]. Our pressure device consists of a custom-molded silicone with up to three separate adjustable pressure mechanisms.

In a similar study to ours using a methyl methacrylate stent, Kadouch et al. had an overall success rate of 83 % with a mean follow-up of 23 months. In our study, we observed a 71 % success rate with a mean follow-up of 8.5 years. It might thus appear that our method is less effective than theirs, but as we have seen in this study, keloid recurrence can occur as late as 3 years after primary therapy. The success rate of Kadouch et al. may thus in fact be lower than presented. We advise a long follow-up to evaluate the effectiveness of therapy methods in scar treatment.

While a positive family history for keloids has been associated with keloid recurrence, we were not able to confirm this [16]. On the other hand, we could confirm that darker-skinned patients were more prone to recurrence than lighter-skinned patients. This appears logical since people with a higher Fitzpatrick skin type also have a higher incidence of keloids [4]. We also have found that keloids resulting from otoplasty had a higher recurrence rate than other causes. This is probably related to a more extensive damage to the soft tissue of the ear in comparison to smaller injuries caused by ear piercings for example. Another possible explanation is a more prolonged immunologic reaction on dissolvable suture material used in otoplasty. As for the therapy compliance rates, there is a trend towards a correlation between compliance and nonrecurrence, although this does not reach statistical significance. This further highlights the link between therapy effectiveness and outcome, and if true, doctors should encourage patients to wear the device as long as needed.

Using the POSAS score, we observed a statistically significant improvement in all the items of the POSAS between before therapy and the last follow-up. This confirms the efficacy of our custom-molded device. Since the total POSAS score before therapy showed no statistically significant difference between the recurrence and nonrecurrence groups, we can conclude that recurrence does not depend on clinical presentation upfront. Therefore, someone with a high or low POSAS does not predict recurrence. In other words, it does not matter how bad the POSAS score is preoperatively; the chances for success are equal.

In addition, patients rated the comfort, appearance, and overall opinion as acceptable, but people with recurrence had less comfort. A possible explanation could be that the adjustments had not been made appropriately, and therefore, the containment of the wound was suboptimal, resulting in a higher chance of recurrence. Put differently, the compression in these patients was maybe not centered on the point of interest.

Sixty-one percent of patients first complained about discomfort which seems very high; however, because our device can adjust the pressure, we can relieve this, in contrast to most pressure ear clips lacking the ability of applying accurate and independent pressure on the

ear keloids. Another benefit is the prevention of severe complications such as tissue necrosis with permanent damage, because of the application of a homogenous pressure. Therefore, it is our opinion that our custom-molded ear clip, in terms of effective applied pressure on the keloids, is superior to conventional ear clips.

The main drawback is the size of our custom-molded ear clip and the relatively unattractive aesthetic appearance of this device. In comparison to Park's device using magnets [18], our device is more obvious and unattractive, but as previously prescribed, Park's device lacks the ability to adjust the pressure. However, most of the other existing devices such as the U loop pressure clip [17] and the methyl methacrylate stent [16] are, in our opinion, a bit more or equally cosmetically appealing. However, most of the patients were satisfied with this therapy in general. To support this finding, we have found that 37.5 % of patients with recurrence would choose the treatment again. This means that even if we consider recurrence as a failure, actually for the patient this is not the case. These patients are satisfied or at least free from the keloid for several years and if they would have to undergo the treatment again, they would.

In summary, in this study, we show that the advantages of our custom-molded pressure ear clip are the retro-auricular treatment option, adjustable pressure, and minimal severe complication rate. The main disadvantage is the unattractive appearance. The results of adjuvant pressure therapy with our ear clips are comparable with the recurrence rates of other studies recently published [16, 18]. The strength of this study is the long follow-up. Since the number of patients is moderate, a larger patient group is needed to more accurately investigate and determine the efficacy of adjuvant pressure therapy for treatment of ear keloids.

Conflict of interest The authors certify that they have no affiliations with or involvement in any organization or entity with any financial interest. The authors hereby disclose any commercial interest that they may have in the subject of study and the source of any financial or material support.

Ethical standards All patients gave written informed consent prior to inclusion in the study. The study was approved by the Medical Ethical Committee of the University of Maastricht and has been performed in accordance with the ethical standards laid down in the Declaration of Helsinki.

References

1. Cohen IK, Keiser HR, Sjoerdsma A (1971) Collagen synthesis in human keloid and hypertrophic scar. Surg Forum 22:488–489
2. Goldwyn RM (1981) Keloid. Plast Reconstr Surg 68(4):640–641
3. Zuber TJ, DeWitt DE (1994) Earlobe keloids. Am Fam Physician 49(8):1835–1841
4. Atiyeh BS, Costagliola M, Hayek SN (2005) Keloid or hypertrophic scar: the controversy: review of the literature. Ann Plast Surg 54(6): 676–680
5. Bayat A et al (2004) Description of site-specific morphology of keloid phenotypes in an Afrocaribbean population. Br J Plast Surg 57(2):122–133
6. Akoz T, Gideroglu K, Akan M (2002) Combination of different techniques for the treatment of earlobe keloids. Aesthetic Plastic Surg 26(3):184–188
7. Chalian VA et al (1985) Auricular compression stent. J Prosthet Dent 54(4):560–563
8. Brent B (1978) The role of pressure therapy in management of earlobe keloids: preliminary report of a controlled study. Ann Plast Surg 1(6):579–581
9. Robles DT, Berg D (2007) Abnormal wound healing: keloids. Clin Dermatol 25(1):26–32
10. Recalcati S, Caccialanza M, Piccinno R (2011) Postoperative radiotherapy of auricular keloids: a 26-year experience. J Dermatolog Treat 22(1):38–42
11. Ragoowansi R et al (2003) Treatment of keloids by surgical excision and immediate postoperative single-fraction radiotherapy. Plast Reconstr Surg 111(6):1853–1859
12. Scrimali L et al (2010) Treatment of hypertrophic scars and keloids with a fractional CO2 laser: a personal experience. J Cosmet Laser Ther 12(5):218–221
13. Kassab AN, El Kharbotly A (2011) Management of ear lobule keloids using 980-nm diode laser. Eur Arch Otorhinolaryngol 269(2):419–423
14. Yencha MW, Oberman JP (2006) Combined therapy in the treatment of auricular keloids. Ear Nose Throat J 85(2):93–94, 96–7
15. Savion Y, Sela M, Sharon-Buller A (2009) Pressure earring as an adjunct to surgical removal of earlobe keloids. Dermatol Surg 35(3): 490–492
16. Kadouch DJ et al (2010) Therapeutic hotline: an alternative adjuvant treatment after ear keloid excision using a custom-made methyl methacrylate stent. Dermatol Ther 23(6):686–692
17. Vachiramon A, Bamber MA (2004) A U-loop pressure clip for earlobe keloid. J Prosthet Dent 92(4):389–391
18. Park TH et al (2011) Outcomes of surgical excision with pressure therapy using magnets and identification of risk factors for recurrent keloids. Plast Reconstr Surg 128(2):431–439
19. Yigit B et al (2009) A custom-made silicon mold for pressure therapy to ear keloids. Aesthetic Plastic Surg 33(6):849–851
20. Fujii T et al (2006) Quality of life in patients with Japanese cedar pollinosis: using the SF-8 health status questionnaire (Japanese version). Arerugi 55(10):1288–1294
21. Draaijers LJ et al (2004) The patient and observer scar assessment scale: a reliable and feasible tool for scar evaluation. Plast Reconstr Surg 113(7):1960–1965

22. van de Kar AL et al (2005) Reliable and feasible evaluation of linear scars by the Patient and Observer Scar Assessment Scale. Plast Reconstr Surg 116(2):514–522
23. Linares HA, Larson DL, Willis-Galstaun BA (1993) Historical notes on the use of pressure in the treatment of hypertrophic scars or keloids. Burns 19(1):17–21
24. Berman B, Bieley HC (1996) Adjunct therapies to surgical management of keloids. Dermatol Surg 22(2):126–130
25. Chang CH et al (2005) The efficacy of magnetic disks for the treatment of earlobe hypertrophic scar. Ann Plast Surg 54(5):566–569
26. Sela M, Taicher S (1984) Prosthetic treatment of earlobe keloids. J Prosthet Dent 52(3):417–418
27. Russell R, Horlock N, Gault D (2001) Zimmer splintage: a simple effective treatment for keloids following ear-piercing. Br J Plast Surg 54(6):509–510
28. Lapidus SM, Davis RK (1977) A simple dressing for earlobes. Plast Reconstr Surg 59(2):287
29. Hurtado AJ, Crowther DS (1985) Methyl methacrylate stent for prevention of postexcisional recurrent ear keloid. J Prosthet Dent 54(2):245–250